

Application No. 09/737,687

Page 1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Allen, et al.

Application No.: 09/737,687

Group Art Unit: 1626

Filed: 12/14/2000

Examiner: WRIGHT

Title: SALICYLAMIDES AS SERINE PROTEASE INHIBITORS

Attorney Docket No.: 218

Assistant Commissioner for Patents
Washington, D.C. 20231

RECEIVED
MAR 28 2003
TECH CENTER 1600/2900

H/K
4/1/03

Response.

Dear Sir:

This is in response to the final Office Action as mailed by the Examiner on November 20, 2002, which maintained the objection to Claims 1-8 and 10-17 as containing non-elected subject matter. Applicants request reconsideration of this objection. Enclosed is a Petition to extend the time to file this Response. A Petition from Requirement for Restriction under 37 C.F.R. § 1.144 (2003) requesting review of the Examiner's improper restriction requirement has been filed, as well as a Notice of Appeal under 37 C.F.R. § 1.191 (2003), pending resolution of the § 1.144 Petition.

Procedural History.

In an Office Action mailed July 30, 2001, the Examiner required the Applicants to elect one of the following three groups:

- I. Claims 1-8 and 10-17 drawn to compounds of formula I, classified in various classes and subclasses;
- II. Claims 20-27, drawn to a process, classified in various classes and subclasses; and
- III. Claims 9, 18, 19 and 28-31, drawn to a method of use, classified in various classes and subclasses.

In a Response dated October 12, 2001, the applicants elected Group I; Claims 1-8 and 10-17 are in this application. Groups II and III which included Claims 20-27, and Claims 9, 18, 19 and 28-31, respectively, were withdrawn from consideration as drawn to non-elected subject matter.

The Examiner further required in the July 30, 2001 Office Action that the Applicants elect a single disclosed species. In a Response dated October 12, 2001, the Applicants elected Group I and the species found on page 66, line 8, of the specification, namely naphthalene-2-carboxylic acid (6-guanidino-pyridin-3-yl)-amide. The Applicants traversed the election of species requirement to the extent that the Examiner intended that the non-elected species would be permanently withdrawn from consideration.

In a non-final Office Action mailed December 5, 2001, the Examiner rejected Claim 1 as indefinite under 35 U.S.C. § 112 second paragraph. Claims 1-8 and 10-17 of the elected Group I were objected to "as containing non-elected subject matter" and "the remaining subject matter of claims 1-8 and 10-17 ... stands withdrawn from further consideration." The Examiner stated that "[t]his objection may be overcome by limiting the claims to the elected subject matter identified supra."

In a response mailed June 24, 2002, the rejection of Claim 1 was overcome by amendment in accordance with the Examiner's suggestions. The Applicants thus believe the application was put in condition for allowance. Also in the June 24, 2002 response, the Applicants requested reconsideration of the objection to Group I as containing non-elected subject matter. In a final Office Action dated November 20, 2002, the Examiner allowed the amendment to Claim 1. However, the objection to Claims 1-8 and 10-17 as containing non-elected subject matter was maintained. The Applicants respectfully request the Examiner to reconsider for the following reasons.

Arguments.

Restriction Requirement.

The Applicants respectfully submit that there is no statutory, regulatory or procedural basis granting the U.S.P.T.O. the authority to object to a claim under examination on the basis that it contains non-elected subject matter in part. A claim, in its entirety, is either in the application as encompassing elected subject matter or withdrawn from consideration as containing non-elected subject matter. If the elected claims encompass more than one species,

the Examiner may require that the Applicants elect a particular species for examination; but this is a procedural tool and there is nothing found in the statutes, regulations, procedures, or case law which provides that the Applicants must amend the scope of a generic claim to excise non-elected species.

The Applicants direct the Examiner to 37 C.F.R. § 1.141 (2003) and the M.P.E.P. § 809.02(c)(B)(1) (2001), respectively, for a description of proper restriction practice regarding generic claims:

§ 1.141

(a) Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided that the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim.

(Emphasis added.)

§ 809.02(c)

An examiner's action subsequent to an election of species should include a complete action on the merits of all claims readable on the elected species.

....

(B) When a generic claim is subsequently found to be allowable, and not more than a reasonable number of additional species are claimed [in different claims], treatment shall be as follows:

(1) When all claims to each of the additional species are embraced by an allowable generic claim as provided by 37 CFR 1.141, applicant must be advised of the allowable generic claim and that claims drawn to the nonelected species are no longer withdrawn since they are fully embraced by the allowed generic claim.

(Emphasis added.) The Applicants point out the “a reasonable number” of species refers to those *specifically* claimed and not to the number of species embraced by the generic claim. The Applicants submit that these sections from the Code and M.P.E.P. describe the proper procedures for restriction practice regarding genus and species claims. Hence, the examiner may require an applicant to provisionally elect a species for examination. If the elected species is ultimately

found patentable, then examination is extended to the provisionally withdrawn subgenera. Only after a species is examined on the merits and found unpatentable may the Examiner permanently withdraw it and reject the generic claim which reads on the unpatentable species. This rejection may be overcome by amending. Thus, the prior art search is not extended unnecessarily and the applicant's invention, as he or she contemplates it, is examined on the merits.

Relying on this procedure as described by the P.T.O. itself, the Applicants submit that the restriction requirement in this Application is improper. The issue here is whether the U.S.P.T.O. has the authority to compel an applicant to divide up her or his generically claimed invention pursuant to an election of species requirement. The Applicants submit that the P.T.O. does not have this authority. If, in order to comply with the Restriction Requirement, the Applicants are compelled to divide their generically claimed invention into various subgenus claims, the Applicants will not have their claims examined in the form that they believe to best define their invention. Decisions by the Patent and Trademark Office Board of Patent Appeals and its reviewing court clearly hold that a restriction requirement which compels an applicant to divide a generic claim for the purposes of excising non-elected subject matter is improper and that such a procedure amounts to a rejection.

The Applicants direct the Examiner's attention to *In re Haas*, 486 F.2d 1053 (C.C.P.A. 1973) (*Haas I*) (further proceedings at *In re Haas*, 580 F.2d 461 (C.C.P.A. 1978)) to support of their position regarding the improper restriction requirement. *Haas I* was an appeal to the United States Court of Custom and Patent Appeals from a dismissal by the Board for lack of subject matter jurisdiction over an appeal from an examiner's objection to claims. The examiner in *Haas I*, relying on 35 U.S.C. § 121, objected to two Markush claims as each being drawn to multiple patentably distinct inventions and withdrew them both from further consideration. A species claim was allowed and a "narrow Markush claim, encompassing only those reactive moieties similar to the allowed species, was suggested" (*Haas I* at 1054). The applicants were then compelled to cancel the original claims. The prosecution history for this Application follows the facts in *Haas I* very closely. Here, the Examiner required the Applicants to elect a single disclosed species from within claims containing Markush groups and all non-elected species were required to be withdrawn permanently from further consideration. The Applicants elected a single species for examination purposes with traverse but did not cancel the non-elected

species from the claims. Each claim of Claims 1-8 and 10-17 subsequently was objected to as containing non-elected subject matter *within* each claim.

The *Haas I* court held that an objection can deny the applicant's substantive rights and amount to a rejection of those claims. In *Haas I*, as well as in this Application, the requirement to cancel non-elected species from within a single claim was made permanent. This amounted to a rejection as each claim, in its entirety, would never be examined on the merits, essentially denying the patentability of the Applicants' invention as they see fit to claim it. The court held,

[t]he absolute "withdrawal" herein cannot properly be categorized as merely a "requirement" or "objection" and the avenue of review thereby be restricted to petition and judicial examination under 5 USC § 701-6. An examiner's adverse action of this nature is a rejection, a denial of substantive rights. Review thereof must fall within the jurisdiction of the board.

Id. at 1056. The Examiner's requirement to cancel the non-elected species from the generic claim thus amounts to a rejection of the claims and is a denial of substantive rights which is improper and appealable to the Board and its reviewing court.

The Court in *In re Weber*, 580 F.2d 455 (C.C.P.A. 1978) addressed this same situation. The examiner asserted that Weber's claim 1 "embraced 24 enumerated independent and distinct inventions" (*id.* at 456) and subsequently rejected it for misjoinder under 35 U.S.C. § 121. Upon appeal the Board affirmed that "§ 121 was an adequate legal basis for the examiner to reject a single claim 'embracing' more than one independent and distinct invention." (*Id.* at 457). However, upon appeal to the United States Court of Customs and Patent Appeals, the court held that the restriction requirement was improper, stating:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

Id. at 458 (emphasis added). The Weber court is particularly clear that the division of a single claim by the examiner, with the nonelected subject matter being withdrawn from further consideration, is not permissible.

Ex parte Holt, 214 USPQ 381 (Bd. App. 1982) (*Holt I*) also supports this position. In *Holt* the Board of Appeals followed *Weber* and *Haas I* stating that 35 U.S.C. § 121 does not give the Patent Office the authority to reject or otherwise refuse to examine a claim. The Board declared, "[i]t is clear from *Haas I* that regardless of the language employed by the examiner, the refusal to examine a claim is, in effect, a rejection of that claim." (Emphasis added.) In *Holt I* the applicant tried to recapture through reissue subject matter that had been improperly restricted from the application. The Board later reversed its allowance of the reissue on the grounds that the applicant knew or should have known that the restriction requirement was improper and so was not error under 35 U.S.C. § 251. (See *Ex parte Holt*, 218 U.S.P.Q. 747 (B.P.A.I. 1982).) The Board, however, left untouched its holding that the restriction requirement was not proper.

Rohm and Haas Company v. Robert Gottschalk, Commissioner of Patents, 504 F.2d 259 (D.C. Cir.1974) also follows *Hass* and *Weber*. In that case, the applicants' petition to the commissioner to review the restriction requirement was denied. Rohm and Haas unsuccessfully appealed to the District Court and was left with no other recourse until *Weber* and *Haas* were decided. Subsequently, the applicants appealed to U.S. Court of Appeals for the District Court of Columbia which held: "[i]n *re Haas* is directly in point with our instant appeal as appellee conceded at oral argument. Since we agree with the reasoning of *In re Haas, supra*, we vacate the District Court judgment in this case and direct the District Court to remand this appeal to the Patent Office for further proceedings in the light of *In re Haas*." *Rohm and Haas Company* at 260. Again, there is no doubt as to the courts' position on the impropriety of permanently withdrawing nonelected subject matter from a claim before it has been examined on the merits.

In light of *Weber* and *Haas*, the Patent and Trademark Office revised restriction practice with respect to generically claimed inventions. The proper procedure for restricting a generic claim is delineated in M.P.E.P. § 803.02 (2001). In this regard the Appellants direct the Board to M.P.E.P. § 803.02, paragraphs 4 and 5, which states:

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD or CE. The

Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended.

(Emphasis added.) Hence, the examiner may require an applicant to elect provisionally a species for examination. If the elected species is ultimately found patentable. Then the examination is extended to the provisionally withdrawn subgenera. If, on the other hand, the elected species is found unpatentable, the generic claim and claims to the elected species are rejected and claims to the non-elected subgenera are withdrawn from further consideration. The applicant may overcome this rejection by amending the generic claim to exclude the unpatentable species. If after reconsideration of the amended claim a second species is found unpatentable, the claim is rejected and the action is made final. Thus, the prior art search is not extended unnecessarily and the applicant's invention, as he or she contemplates it, is examined on the merits.

The Examiner referred the Applicants to M.P.E.P. § 806.04(f) (2001), "Claims Restricted to Species, by Mutually Exclusive Characteristics" as the basis for the withdrawal of the nonelected subject matter. Section 806.04(f) states, in part, that "[t]he general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, which a second claim recites limitations disclosed only for the second species and not the first," (emphasis added). Please note the plurality of "claims" in the above excerpt and the fact that the section is referring to restriction between more than one species claims and not within one genus claim. The Applicants submit that § 806.04(f) does not support the proposition that the Patent Office has the authority under 35 U.S.C. § 121 (2002) to withdraw permanently non-elected species and compel an amendment narrowing the scope of an applicant's generically claimed invention.

To the contrary, the Board of Patent Appeals and Interferences and its reviewing court have categorically held that § 121 grants no such authority. The court in *In re Watkinson*, 900 F.2d 230, 232 (Fed.Cir.1990), reaffirmed this when it wrote: "[u]nder *In re Weber*, ...[at 458] and *In re Haas*, ...[at 464], it is *never* proper for an examiner to reject a Markush claim under 35

U.S.C. § 121. Section 121 simply does not authorize such a rejection. *Id.*" (Emphasis in the original). *Weber* at 460 emphasizes this point: "[d]ealing, as it does, with requirements for restriction, § 121 says nothing whatever about the rejection of claims, a matter entirely separate from restriction." The court has been unequivocal in its rejection of the use of § 121 to reject matter within a Markush-type claim.

Under the authority of 37 C.F.R. § 1.142(b), the Examiner carved out a subgeneric concept, inclusive of the elected species, presented it to the Applicants, and withdrew the remaining subject matter of Claims 1-8 and 10-17 from further consideration in an Office Action dated December 5, 2001. The Applicants respectfully point out that § 1.142(b) provides that "[c]laims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration," (emphasis added). Please note that § 1.142(b) refers to "claims" being withdrawn. Section 1.142(b) does not provide, however, that subject matter within one claim may be permanently withdrawn from a generic claim.

In this Application, the Examiner goes further by drafting a claim for the Applicants. Hence, the Examiner, rather than the Applicants, defines the form in which the invention is claimed. The Applicants respectfully submit that such an action is improper. An applicant has a right to have each claim examined on the merits in the form she or he considers to best define her or his invention. (See 35 U.S.C. § 112, second paragraph (2002).) It is not in the Examiner's purview to define the Applicant's invention for them. The Applicants refer the Examiner to *In re Wolfrum*, 486 F.2d 588, 591 (C.C.P.A. 1973) where the court stated "[u]nder this provision of § 112, the scope of the subject matter is governed not by the examiner's conception of the 'invention' but by that 'which the applicant regards as his invention.'" Also *Weber* at 458 speaks to this issue: "[a]n applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention." Here the Examiner has drafted a genus claim for the Applicants to the Examiner's own liking and in doing so defines the invention for the Applicants. The Applicants respectfully submit that this action is clearly improper.

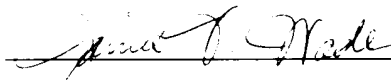
Finally, the Examiner stated, "to consider all the subject matter presented would indeed be burdensome to the Examiner as numerous classes and subclasses would be involved as would numerous searches in the literature." The Applicants respectfully submit that when there is a

conflict between an applicant's statutory right to claim the subject matter of her or his invention as she or he sees fit and the Patent Office's power to regulate the workload of its Examiners, the rights of the applicant must prevail. The Applicants are mindful of the Patent Office's interest in limiting the burden of the examination in each application. The Court in *Weber* recognizing this interest stated, "[e]ven though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee." *Weber* at 458. However, the court went on to state that "... in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount." *Id.* at 458-459. The Applicants submit that their right to claim generically their invention prevails over the Patent Office's power to restrict under § 121.

The Applicants have searched without success for some sort of statutory or judicial authority supporting the propriety of the Examiner's objection. To the contrary, the authority decisively demonstrates that the present objection to the Claims is improper. Accordingly, the Applicants submit that there is no basis for the objection to Claims 1-8 and 10-17 and respectfully request that the objection be withdrawn.

Respectfully submitted,

Date: 3-19-03



Janice V. Wade
Agent for Applicants
Reg. No. 50,606

CELERA GENOMICS
180 Kimball Way
South San Francisco, CA 94080
Tel: (650) 866-6228
Fax: (650) 866-6651